PROMISING PRACTICES FOR PROMOTING UTILIZATION OF COVID-19 MONOCLONAL ANTIBODY TREATMENTS

Duke | MARGOLIS CENTER *for* Health Policy

Equitable State Allocation

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INTRODUCTION

In response to surging demand for limited monoclonal antibody (mAb) therapies as the Delta variant spread across the United States, the Assistant Secretary for Preparedness and Response (ASPR) of the US Department of Health and Human Services (HHS) announced a shift to state and territorial coordination of mAb allocation to ensure consistent availability of these therapies across the country. The current state- and territory-coordinated allocation is similar to the process used from November 2020 through February 2021—a process that built off strategies tested during the earlier deployment of the antiviral remdesivir. From March 2021 until September 2021, mAb therapy administration sites were able to directly order the product. The recent transition from direct ordering back to state and territory-coordinated allocation was prompted by mAb therapy demand greatly outpacing supply. This decision allowed state leaders flexibility and oversight to equitably allocate potentially scarce therapeutic resources to communities and individuals most at risk of serious illness from COVID-19.

However, states have varying levels of experience in overseeing mAb allocation, with many jurisdictions having previously relied on widespread use of the product by health systems, infusion centers, and other providers ordering their mAb treatment supply directly from the Federal government. Dynamic supply of and demand for mAb therapy will continue to influence state decision-making, requiring states to monitor new developments and stay flexible to make appropriate adjustments to allocation approaches. In addition to making critical decisions around allocation of these therapies, states are also undertaking a range of strategies to support greater access to these therapies, including mitigating access challenges among historically marginalized populations, including elderly populations, people who are disabled, people who are unhoused, immigrant populations, and people living in rural areas.

This issue brief provides considerations and promising practices for state and territorial leaders to respond to this shifting landscape of demand and supply while delivering efficient and equitable allocation of mAb therapies. Although increasing uptake of testing and vaccination remains a key priority for state leaders, equitable allocation of mAb therapies is critical for reducing hospitalizations and deaths caused by COVID-19 case surges—especially among unvaccinated individuals and vaccinated individuals unable to mount a full immune response.

The following considerations align with previous reports describing equity-informed guiding principles for vaccine and testing rollouts and build on a March 2021 issue brief outlining considerations and promising practices specifically for mAb allocation by states, which was published in partnership with the National Governors Association. This issue brief is informed by discussions with state officials overseeing the allocation of mAb therapies; officials from the Association of State and Territorial Health Officials (ASTHO); and the Duke-Margolis COVID-19 mAb Working Group, which includes representatives from health care systems, multi-stakeholder engagement efforts, antibody developers, HHS, the Centers for Medicare and Medicaid Services, infusion provider associations, and others. A full list of the Working Group's current member organizations is included at the end of this brief.

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EVOLVING ALLOCATION CHALLENGES AND STRATEGIES FOR OVERCOMING THEM

Beginning in November 2020 with the initial emergency use authorization (EUA) of Eli Lilly's monoclonal therapy bamlanivimab, many states and territories implemented strategies to coordinate with health systems to determine eligible populations, allocate limited therapies to health system partners, and develop strategies for improving availability of therapies for populations placed at greatest risk of serious illness from COVID-19. The following sections describe how states have addressed evolving challenges related to data tracking, patient prioritization, distribution logistics, and community engagement to ensure equitable availability, access, and utilization.

Improving Data Collection and Exchange

Challenge: Collecting accurate data on availability, utilization, and demand that support evidence-based approaches for allocation

In the shift to state-led coordination, many states experienced challenges in accurately tracking where mAb therapies had been distributed and used. To address this challenge, many states shifted to centrally-run systems that support ordering and tracking of mAb therapeutics, including reporting processes to capture data that had previously been inconsistently reported to Federal entities. For example, Tennessee relied on over 200 privately-run sites that were directly receiving allocations. After the shift to state-led coordination, Tennessee improved data collection from these privately-run provider sites by requiring all providers receiving allocations to enroll in TeleTracking—a software within the HHSProtect platform for tracking mAb utilization and inventory. Nearly all privately-run sites enrolled, providing the state more complete data on supply and utilization of mAb therapies.

State-run ordering processes have allowed states to distribute to providers on a weekly or biweekly basis—based on available supply—with the ability to shift allocations based on "hot spots" or urgent needs. For example, Utah's state-run mAb stockpile and distribution system allows the state to onboard new providers and shift allocations based on emerging needs like outbreaks in long-term care facilities (LTCF). Additionally, as a condition for receiving mAb supply through the state, Utah requires sites to report the number of mAb treatments available, administered, and needed for the coming week. Most sites have complied with this data reporting requirement, enabling better allocation of mAb therapies based on demand and better tracking of utilization across the state. In New Hampshire, a similar state health department-run mAb stockpile is managed in partnership with the state's psychiatric hospital, which has ample cold storage capacity and is centrally located so mAb therapies can be efficiently transferred for acute needs, particularly for LCTF.

Additionally, collecting reliable data on availability, patient referrals, and utilization for mAb therapies across racial and ethnic as well as geographic demographics can improve allocation of resources to historically marginalized populations. The Michigan Department of Health and Human Services (MDHHS) emphasized the collection of basic demographic and clinical information on every patient that received mAb therapy, and acquired data on approximately 70 percent of patients receiving therapies. Analyzing these data, MDHHS found the state mAb therapy program was not reaching Black residents, which prompted a partnership with the Federal government to open treatment sites in hospitals specifically serving Black communities. Subsequently, the percentage of Black patients who received mAb therapy more than doubled from seven to 17 percent, making uptake more proportional to statewide demographics and COVID-19 cases.

Ensuring accurate data tracking is also tremendously important for states to have second opportunities at ordering supply from ASPR via a newly instituted process wherein ASPR reallocates mAb therapy within a given distribution cycle. Each Friday, ASPR identifies mAb therapy not designated for allocation by states. State health department officials can request a share of these "leftover" mAb therapies if their state utilized at least 70 percent of their allocation from the previous distribution cycle and possess less than three weeks supply of product based on utilization and current inventory. Furthermore, in situations where treatment sites have a surplus of mAb supply, centralized filing and coordination at the state level can help facilitate secondary intrastate distribution to ensure that doses are not wasted. For example, Texas and AmerisourceBergen returned unused doses to a centralized pharmacy run by the Texas Department of State Health Services to be redistributed as needed.

Challenge: Capturing clearly defined data elements

Providers' differing interpretations of required data elements can lead to inconsistent data collection approaches that compromise the quality and reliability of reported data, as well as efforts to identify equity gaps in distribution. To address this challenge, states can provide clear, precise definitions regarding the information providers are to collect. For example, after an inventory review at each mAb site, Maryland discovered differences in how providers counted supply resulting in an incomplete picture of availability across the state. Providers specifically differed in whether one or two mAb therapy doses constituted a treatment. By establishing consistent definitions and processes, Maryland verified accurate data to inform site availability, utilization, and demand.

Determining Patient Eligibility and Prioritization

Challenge: Developing a consistent qualitative and/or quantitative method of prioritization

The shift to state-led distribution coincided with a peak in cases for many states experiencing the greatest impact of the Delta variant, leading to concerns that states and distribution sites might need to implement crisis standards of care or protocols for determining eligibility when demand for mAb therapies exceeded supply. Although most states were able to meet demand even during peak utilization, many states did develop guidance for providers to prioritize patients in the event of excess demand. In doing so, many health officials consulted the NIH COVID-19 Treatment Panel guidelines, which are based on clinical risk assessment whereby COVID positive patients are prioritized ahead of post-exposure prophylactic patients. These guidelines also prioritize unvaccinated, incompletely vaccinated, and vaccinated and immunocompromised individuals. Providers will likely only refer to these guidelines when there are logistical and supply constraints necessitating triage usage of mAb therapies.

Many states have adopted the NIH guidelines or used them as a starting point to help guide decisions in supply-constrained environments. For example, Tennessee planned to prioritize using NIH guidelines if there were supply or logistical constraints. Although Tennessee did not implement NIH guidelines on a wide scale, the Tennessee Department of Health successfully integrated clinical risk assessment and allowed for provider discretion. Minnesota built on the NIH guidelines by developing an ethical framework that outlines an approach to address logistical constraints. Health officials can also consider piloting a point system or utilizing a set of clinical predictors to treat patients who are most at risk for progressing to severe COVID-19 and requiring hospitalization. Utah has employed one such point system for stratifying risk of patients progressing to severe COVID-19 infection.

Additionally, many health systems have also produced and refined their own patient prioritization guidelines—taking into consideration local community spread and case burden. States can engage with these referring and administering health care professionals to preemptively plan for logistical or supply constraints and assess how well NIH, state, or health system guidelines fit with local needs. Strengthening communication between mAb therapy administration sites and the referring provider base would be valuable. Michigan benefitted from enhanced communication between the referring provider base and mAb therapy regional administration sites during the initial period of state-coordinated distribution. Furthermore, states can use existing health professional and provider organizations to help close the gap between referral and treatment, akin to steps taken by Alabama, Michigan, Maryland, and Texas during the first period of state-coordinated distribution in early 2021. Additional multi-stakeholder engagement efforts supported by the Federal government have worked to facilitate bidirectional communication channels between health care professionals and state/local health authorities.

Addressing Logistical Challenges in Distribution and Access

Challenge: Reaching people where they are

One of the most consistent logistical barriers to accessing mAb therapies in many communities is a lack of transportation. To address transportation barriers, municipality-owned and contracted vehicles such as shuttles, vans, and school buses

can drive individuals to mAb sites. The state can play a coordinating role by working with counties, municipalities, and community groups to address local challenges. Another important strategy for meeting the needs of individuals with significant mobility barriers is to support mobile unit administration sites and home care settings, which can address additional barriers that transportation-based solutions do not resolve. For example, a multi-stakeholder effort led by Cape Cod Healthcare and state and federal partners provided a mobile unit to treat patients in Barnstable County, Massachusetts with mAb therapies. The mobile unit effectively targeted a gamma variant-driven outbreak, demonstrating how nimble these types of mobile approaches can be in response to a changing pandemic. In addition, Massachusetts coordinated extensively with LTCF to ensure they have mAb availability, shifting rapid response team nurses to higher-risk environments to support infusion capacity. Berkshire County developed a just-in-time approach to connect patients at testing sites who receive a positive result from a rapid test and meet inclusion criteria, with mAb infusion sites located adjacent to the region's three emergency departments. This approach has made Berkshire Medical Center the leading provider of mAb in the Commonwealth. Utah also successfully deployed mobile administration teams to memory care facilities. Memory care facilities are high-risk environments, and by bringing the product to the patients, Utah can alleviate outbreaks in the broader community.

Challenge: Scaling infrastructure to reduce disruptions in mAb therapy availability

As cases declined in spring and early summer 2021, demand for mAb therapies significantly decreased and many sites were shut down – meaning many states needed to rapidly scale infusion infrastructure in responding to rising cases and hospitalizations during the delta variant outbreak. In preparing for subsequent outbreaks, states and territories can construct treatment delivery infrastructure—for care in outpatient, mobile, and LTCF settings—that can be easily scaled up and down depending on community needs. Infrastructure that needs to be scaled includes treatment site locations, staffing, and patient utilization data collection and analysis.

Sustainable infrastructure for providing mAb therapy will require dedicated planning for many care settings. States can convene community partners, employers, and other stakeholders to assess community needs and map community assets when deciding on treatment site locations. For example, Texas engaged with a wide network of health care providers spanning hospital and health systems, nursing homes, and rural hospitals. Combined with regional infusion centers, Texas increased mAb utilization through this wider network of sites. Tennessee has had a baseline 50-75 privately run sites operating last winter, which scaled up to 221 sites during the delta variant surge.

Challenge: Staffing constraints to scale site locations

In addition to considerations for scaling treatment site locations, states can also identify solutions for ameliorating potential staffing and workforce challenges that can impact access and availability of mAb therapies. During the pandemic, health care professionals have experienced significant burnout and turnover, resulting in difficulties in health system administration of infusion sites. Maryland found that it was harder to identify nurses to staff administration sites, and broadly opened up the capacity for any provider registered with HHS to order and receive mAb therapy. By onboarding new providers, Maryland was able to address staffing challenges and potential disruptions to access. Utah also encountered staffing shortages for mAb treatment administration due to the high cost of staffing rural and remote locations. The state worked with the Federal government to overcome these barriers, requesting mAb treatment strike teams for deployment to remote locations.

Community Engagement

Challenge: Engaging historically marginalized populations to improve equitable access

Novel health care interventions are often met with public skepticism and mistrust due to structural racism and discrimination that people experience in their encounters with health systems. In addition, interventions are often allocated within existing health care networks and pharmacies that do not reach many historically marginalized communities. Partnerships with community leaders who understand local attitudes and perceptions can therefore help

to inform mAb therapy distribution, outreach, and education efforts by bridging the health equity gap. For example, faith-based leaders like Maryland's City of Praise Family Ministries have partnered with state and local governments as part of COVID-19 mAb access efforts, pointing the way forward for other similar types of community- and faith-based initiatives. States can also provide clearer information regarding cost-sharing while amplifying this message through existing community networks. Currently, there is no cost-sharing for mAb therapies for Medicare or Medicaid beneficiaries; however, financial concerns among community members stem from accounts of individuals receiving bills from private insurers for administration of treatments. This lived experience can deter other community members from seeking mAb therapies, especially if they are uninsured or underinsured. Providers can alleviate these financial concerns by communicating the current payment structure for mAb therapy, as well as understanding the HRSA reimbursement system for uninsured individuals.

Challenge: Raising mAb therapy awareness through culturally and linguistically responsive messaging

While the CDC has designated broad high-risk categories that qualify many people for mAb therapy, members of the local population may not realize that they are eligible due to existing disparities in access to health systems and misinformation. Community leaders can support state efforts to reach eligible individuals who are disconnected from the health system through raising awareness and improved communication efforts. For example, states can develop patient prioritization guidance and communicate to the public through existing community platforms to increase awareness of available mAb therapies. Culturally and linguistically responsive messaging can help communicate why mAb therapy is safe and effective for treating COVID-19, as well as information for how the treatment works and when it should be received (i.e., within 10 days of testing positive or exposure). This messaging should be coupled with broader public health efforts that emphasize the fact that mAb treatments are not replacements for vaccination. Minnesota's webpage outlining mAb therapy, for example, is translated into four languages. The state also launched the Minnesota Resource Allocation Platform (MNRAP) as an online resource that allows any Minnesotan to determine their mAb eligibility. Providers, caregivers, and patients can all use MNRAP to find the nearest administration site with open appointments. In another example, Tennessee distributed flyers advertising mAb therapy to any patient with a positive COVID-19 test.

Challenge: Identifying community-based treatment sites that are welcoming for patients

As states choose where to allocate their limited supply of mAb therapies, they can complement privately run sites with publicly run operations and locations. States can collaborate with community-based clinics and organizations to identify trusted and convenient community spaces to locate mAb therapy sites. Idaho partnered with Heritage Health and Northwest Specialty Hospital to open a mAb site at the rural Coeur d'Alene Fairgrounds. In addition, staffing sites with multilingual and multicultural individuals and reducing the size of administration sites can increase comfort level among individuals seeking mAb therapy. For example, Tennessee found that large hospital sites were intimidating for patients, and thus it was crucial to support privately run sites in smaller, rural counties.

CONCLUSION

As the pandemic continues to evolve – in terms of case rates, therapeutic options, and public policy response efforts – states and territories can use mAb therapies to treat individuals at high risk for severe disease. In continuing to support efficient and equitable access to mAb therapies into future phases of the pandemic, states can proactively address challenges in data tracking, patient prioritization, allocation logistics, and community engagement. States can optimize processes for collecting and standardizing data on mAb therapy availability, utilization, and demand. By establishing patient prioritization guidelines, states can help administration sites triage use of mAb treatments when there are supply constraints. In overcoming logistical issues, states can adapt treatment site location, size, and staffing guidance to connect with eligible patients. To sustain community engagement, states can thoughtfully reach out to historically marginalized populations, be mindful of appropriate messaging, and locate hospitable sites for treatment. While a state-controlled allocation process may be necessary for ensuring equity when there is excess demand for limited therapeutic resources, states can also plan in parallel for a return to normal commercial supply chain distribution processes when feasible.

Applying experiences and lessons learned from implementing state-run allocation of mAb therapies can provide strategies for all states and territories to rapidly reduce access barriers to mAb therapy and inform impending approaches for allocation of oral antiviral therapies.

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DISCLOSURES

Mark B. McClellan, MD, PhD who directs the Duke-Margolis Center for Health Policy, was Commissioner of the Food and Drug Administration from 2002-04 and Administrator of the Centers for Medicare and Medicaid Services from 2004-06. He is an independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.